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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,548	05/29/2001	Gunnar Grue-Sorensen	P 277978	2538

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EXAMINER

BADIO, BARBARA P

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 11/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/787,548

Applicant(s)

GRUE-SORENSEN ET AL.

Examiner

Barbara P. Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8, 10-15 and 21-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8, 10-15 and 21-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13. 6) ☐ Other: ____

Final Office Action on the Merits

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 101

2. The rejection of claims 7, 17 and 18 under 35 USC 101 as being directed to non-statutory subject matter is made moot by the cancellation of the instant claims.

3. The rejection of claims 1-6 and 8 under 35 USC 101 as being directed to non-statutory subject matter is withdrawn.

Claim Rejections - 35 USC § 112

4. The rejection of claims 9, 16, 19 and 20 under 35 USC 112, second paragraph is made moot by the cancellation of the instant claims.
5. The rejection of claims 10-14 under 35 USC 112, second paragraph is withdrawn.
6. The rejection of claim 15 under 35 USC 112, second paragraph is maintained and claim 21 is rejected under 35 USC 112, second paragraph.

The definition of formula I is missing from claims 15 and 21 and, thus, the claims would be dependent on the specification for meaning.

It is noted that applicant indicated that all of the pending claims are depended from amended claim 1. However, the instant claims are not depended on claim 1 as stated by applicant.

Claim Rejections - 35 USC § 102

7. The rejections of claims 9, 16, 19 and 20 under 35 USC 102(b) over (a) Calverley et al. (WO 91/15475) and (b) Calverley et al. ('629) are made moot by the cancellation of the instant claims.

8. The rejections of claims 10-15 under 35 USC 102(b) over (a) Calverley et al. (WO 91/15475) and (b) Calverley et al. ('629) are maintained and claims 1-6, 8, 21 and 22 are rejected under 35 USC 102(b) over Calverley et al. (WO 91/15475 or '629).

Applicant argues the cited reference fail to disclose or suggest a method of treatment and prophylaxis of osteoporosis and related bone conditions. Applicant's argument was considered but not persuasive for the following reasons.

The vitamin D analogues taught by Calverley et al. (WO 91/15475 or '629) are similar to those of the instant claims. The references teach the use of said vitamin D analogues, having anti-inflammatory and immunodulating effects, in the treatment and prophylaxis of **hyperparathyroidism** (see page 1, paragraph 1, lines 9-10 and page 5,

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lines 15-17, **WO 91/15475**; col. 1, lines 11-12 and col. 3, lines 40-42, '**629**'). The art teaches hyperparathyroidism is characterized by an increased activity of the parathyroid gland resulting in increased production of parathyroid hormone, which results in decalcification of bone, or that osteoporosis is induced by hyperparathyroidism (see for example, Angeletti et al., col. 1, lines 17-29; see attached Abstracts of D'Amour, Fukunaga or Kurabayashi). Because of the relationship between hyperparathyroidism and osteoporosis, the ordinary artisan in the art at the time of the present invention would have the reasonable expectation that treatment of hyperparathyroidism would inhibit the onset of osteoporosis caused by excess secretion of parathyroid hormone.

For this reason and those given in Paper No. 11, the rejections of claims 10-15 under 35 USC 102(b) over (a) Calverley et al. (WO 91/15475) and (b) Calverley et al. ('629) are maintained and claims 1-6, 8, 21 and 22 are rejected under 35 USC 102(b) over Calverley et al. (WO 91/15475 or '629).

Claim Rejections - 35 USC § 103

9. The rejections of claims 9, 16, 19 and 20 under 35 USC 103(a) over (a) Calverley et al. (WO 91/15475) and (b) Calverley et al. ('629) are made moot by the cancellation of the instant claims.

10. The rejections of claims 10-15 under 35 USC 103(a) over (a) Calverley et al. (WO 91/15475) and (b) Calverley et al. ('629) are maintained and claims 1-6, 8 and

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21-23 are rejected under 35 USC 103(a) over Calverley et al. (WO 91/15475 or '629).

Applicant's argument and the examiner's response are as discussed above in #8.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

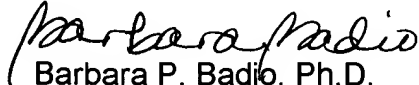
Telephone Inquiry

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308- 2927. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB
November 6, 2003